

POSITIONING OF TB DX: TIERED SYSTEM, INTEGRATED APPROACH

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ANNUAL GLI MEETING, 4th OCTOBER 2010 MERIEUX FOUNDATION, ANNECY



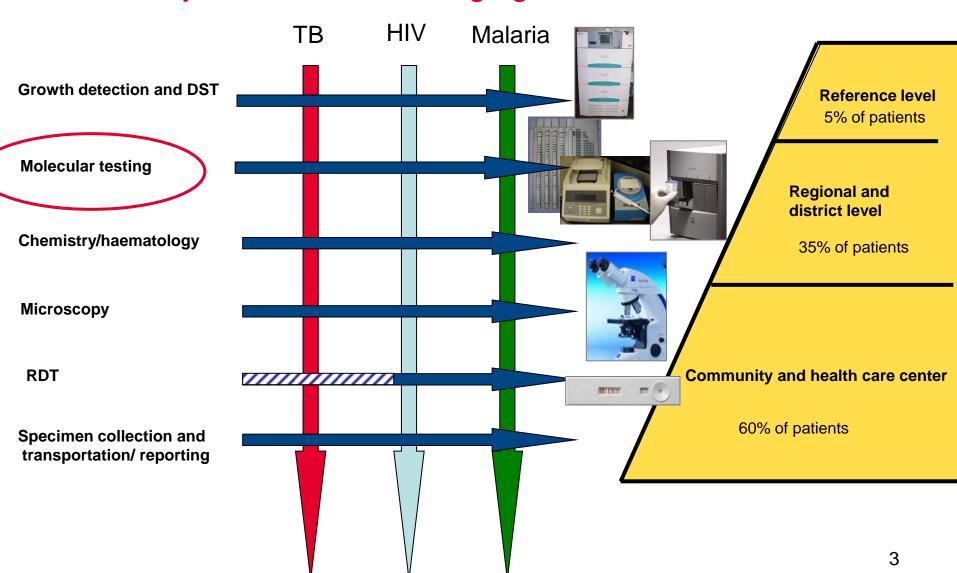
Integrated Laboratory Network Definition

An integrated laboratory network can be defined as one that has the ability to provide all needed primary diagnostic services for care and treatment of patients without requiring them to go to different laboratory facilities for specific tests (under one roof...ideally under one ceiling).

Integrated Laboratory Network



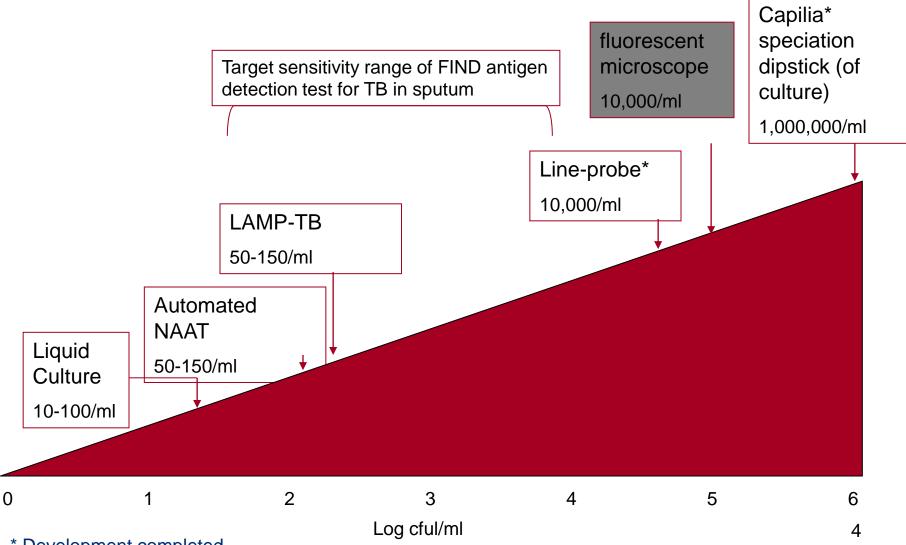
laboratory services and emerging infectious diseases





Importance of early diagnosis:

Sensitivity (cfu/ml) of pulmonary TB tests in portfolio



Development completed











Automated Sample Prep,
Amplification and Detection
<120 minutes

A technology platform:

- TB & Rif Resistance
- Potential for HIV viral load
- Potential for HPV STD

Major advantages in workflow

- fully automated with 1-step external sample prep.
- time-to-result 1 1/2 h (walk away test)
- throughput: up to 16 tests / module / run
- no bio-safety cabinet
- closed system (lower contamination risk)

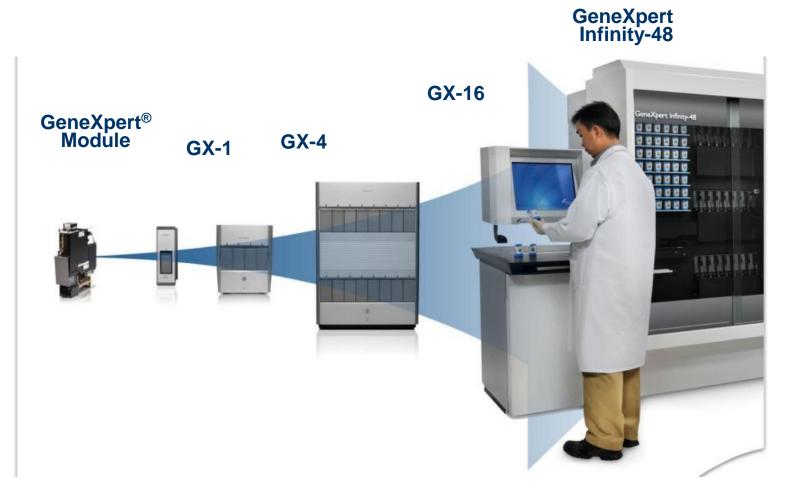
Performance

- specific for MTB
- sensitivity close to culture
- detection of rif-resistance via rpoB gene

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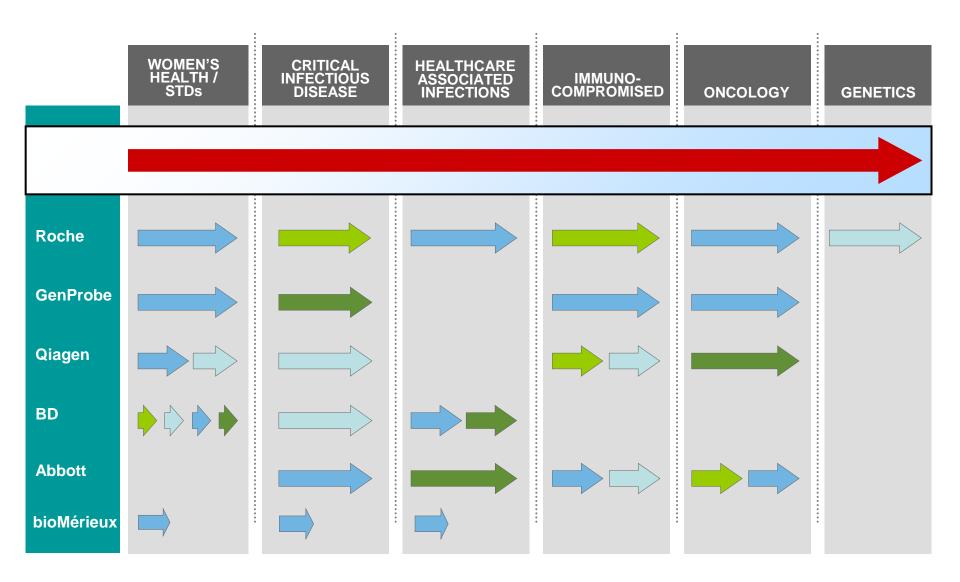






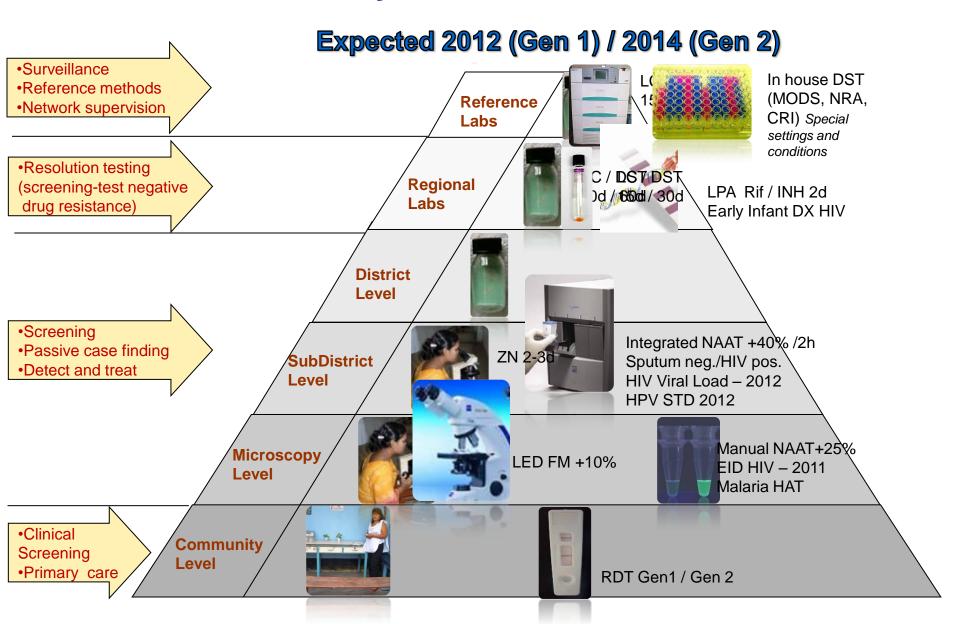
Diverse Testing Needs





Integration of new tools in the tiered health system





Further questions to be answered

foundation foundative new diagnostics

- The eligible patient to be tested
 - Smear + and/ or -
 - Low and high HIV settings
 - Low and high MDR settings
 - Any case or only any drug resistant suspect or only MDR suspects
- Backup culture and DST capacity to follow up MDR/XDR patients
- Specimen referral
- EQA
- Adequate diagnostic algorithm

Integrating HIV-TB diagnostics platforms:









EID for HIV by PCR



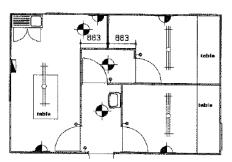
Molecular laboratory in Maseru

Demonstration (Evidence)



WHO (Policy) Implementation (Practice)

March 2007 LC April 2008 LPA June 2007 LC June 2009 LPA November 2007 LC November 2008 LPA April 2009 EID for HIV by PCR



Partners

- WHO
- PIH
- MOH (Lesotho)







National TB Reference Laboratory Maseru, Lesotho: *Integrated TB-HIV (EID) laboratory*



Number of TB diagnostic tests performed (2009 to July 2010)

Testing Platform [~]	Tests performed	MTB Positive	DST tests*	MDR- TB	MDR-patients placed on treatment
MGIT 960- Liquid culture	7081	712	241	116	102
Line probe assay**	652	563	563	117	90

^{*}Only MDR-TB suspects request for DST; ** rapid DST for 'rif' and 'inh'- data includes QA/Training activities ~ In addition: Solid culture and DST for 951 DRS samples and LED FM microscopy demonstration study in 2008-2009



Number of EID HIV* diagnostic tests performed (Jan-July 2010)

Total tests	Positive	Placed on treatment
722	137	35

Early infant Diagnosis of HIV using Dried Blood samples



Punching of DBS cards

DNA extraction

Hybridization reading of plate

^{*} EID-Early infant diagnosis of HIV-1 DNA



Thank you